ADJUSTABLE DEPTH DRILL BIT

FIELD OF THE INVENTION

[0001] The present invention relates to a device for boring a hole into a bone. More particularly, the device is removably attachable to a bone screw hole of a fixation plate and provides a depth limiting function for precision boring of the bone in precise alignment with the bone screw hole of the bone fixation plate.

BACKGROUND

[0002] The use of surgical fixation plates for a variety of orthopaedic applications is a widely accepted. Fixation plates are used by surgeons to stabilize, mend, or align fractured or diseased bones as well as to apply compression or tension to bones and to fuse joints between two or more bones. Typically, fixation plates are fastened to the bone with at least one, and often a plurality, of fasteners such as bone screws that are installed through bone screw holes in the plate. Proper orientation and alignment of the fasteners with the bone plate and secure fixation of the bone plate to the bone can mitigate potential complications after implantation.

[0003] Fixation plates used in spinal applications must be installed with special care. The margin for error in spinal surgery is small, particularly because of the sensitivity of the spinal cord and the risk inherent in performing invasive procedures near the spinal cord. Furthermore, the dimensions of vertebral bone available for receiving fasteners are fairly constrained.

[0004] Screws used to secure the bone plate often must be precisely aligned to facilitate retention of the fasteners in the bone. In some instances the fasteners may be particularly aligned in order facilitate compression between opposing bone segments. Misalignment of the screw within the screw hole of the plate may increase the risk of tissue damage, bone screw failure, fixation failure, and/or bone screw 'back-out' thus increasing the

risk of further injury to the patient and defeating the usefulness of the plate. Locking plates in particular demand the aforementioned precise fastener alignment for proper function.

[0005] Drill guides are often used to facilitate the alignment of bone screw pilot holes and the insertion of bone screws. A typical drill guide attaches or abuts against an associated fixation plate and includes a guide tube,for guiding surgical tools (*e.g.* awls, taps, drills, screws and screwdrivers) toward and through the bone screw hole in the plate. One drawback of the typical drill guide is that it is yet another piece of surgical equipment that must be separately manipulated and accounted for at the surgical suite. A surgeon must manipulate both the tool that is inserted through the drill guide and the drill guide itself, or must have assistance in doing so. This often complicates the surgical procedure, increases the chance for error, and increases the length of surgical procedure.

[0006] Traditional drill guides have included depth limiting arrangements of different sorts for limiting the penetration depth of drills, awls, taps, and other similar bone piercing and boring tools. Currently, there are generally two methods of limiting drilling depth. One consists of an adjustable drill guide that is typically a tubular member with a handle, where the tubular member receives drilling tools therethrough. The tube typically has a stop mechanism that engages with the drilling tool, such as opposing surfaces on the drill guide and on the drill bit that come in contact. Often, one of the components surfaces is adjustable by a threaded mechanism or the like, such that the penetration depth of the component can be adjusted. Another traditional mechanism is a tubular drill guide having a single stop that interacts with different drill bits, where each drill bit has a stop at a different location according to a preferred drilling depth.

[0007] Providing a surgeon with the ability to select a preferred drilling depth increases the efficiency and accuracy of many surgical procedures. This is because many different lengths of screw are used for different procedures and different patient anatomy's.

Furthermore, the depth of a bone screw hole, and the length of a bone screw also depends on the bone quality into which the screw is to penetrate. Yet another consideration is the amount of injury that may result if the drilling procedure and or bone screw penetrate beyond a particular depth. For example, the injury that may result from a misplaced, mis-angled, or misjudged penetration depth of a bone screw placed into a vertebra often can be drastic and permanent.

[0008] Accordingly, a device and method for combining the beneficial functions of a drill guide and a depth limiting guide into a single surgical tool would be highly desirable.

SUMMARY OF THE INVENTION

[0009] According to one embodiment, there is provided a tool comprising a drill bit having a proximal end and a distal end, the distal end configured to cut bone. A housing may also be provided having proximal and distal ends and a bore configured to slidably receive the drill bit. The second end of the housing may be associated with a bone portion into which the drill bit will be extended. An adjustable depth stop assembly may be provided having proximal and distal ends and a bore configured to slidably receive the drill bit, the depth stop further having a portion configured to selectively lock the drill bit to the bore. Thus, when the drill bit is locked to the adjustable depth stop the proximal end of the housing is located a first axial distance from the distal end of the adjustable depth stop so that the first axial distance is proportional to a maximum drilling depth into the bone portion.

[0010] The distal end of the housing may be configured to engage the bone portion directly, or the distal end of the housing may configured to engage a bone fixation element such as a bone plate or a pedicle screw clamping element. The pedicle screw clamping element may be any such element known in the art used to connect a pedicle screw to a spine fixation rod or plate to bridge adjacent vertebra so as to fix their relative positions during, for

example, spinal fusion procedures.

[0011] Where the bone fixation element comprises a bone plate the distal end of the housing may be configured to engage a fastener hole of the plate. The distal end of the housing may further comprising threads configured to engage corresponding threads of the fastener hole. The distal end of the housing may further be configured to engage a screw hole of a bone plate to fix the trajectory of the drill bit with respect to the bone plate and the bone portion. The drill bit may be axially positionable with respect to the housing and the drill bit may also having an extended position in which the distal end of the drill bit extends distally beyond the housing distal end. The drill bit may also have a retracted position in which the distal end of the drill bit does not extend distally beyond the housing distal end.

[0012] The tool housing may comprise a spring having a first surface associated with the housing and a second surface associated with the drill bit, where the spring is operable to bias the drill in the retracted position. The drill bit may have an axial engagement portion configured to engage a corresponding axial engagement portion of the housing to prevent the distal end of the drill bit from moving axially past the proximal end of the housing. The axial engagement portions of the drill bit and housing may comprise a pin and a shoulder, respectively. The housing may further comprise proximal and distal housing portions. The proximal housing portion may have a spring operable to bias the drill in the retracted position, while the distal housing portion may have threads for engaging a bone screw hole of the bone plate. The proximal end of the distal housing further may have protrusion and recess elements configured to engage a respective recess and protrusion elements on the distal end of the proximal housing to rotationally fix the two housing portions. The housing further may have a retainer for removably coupling the proximal and distal housing portions so that the housing portions may be disassembled to facilitate cleaning and/or sterilization of

the tool.

[0013] The proximal housing portion of the tool may further have a proximal end having an increased diameter to allow gripping by a user. The proximal housing portion further may have a proximal stop surface configured to engage the adjustable depth stop assembly.

[0014] The adjustable depth stop may have an adjustment sleeve configured to slidably engage the drill bit, and a shuttle member adapted to be slidable with respect to the adjustment sleeve between a first position in which the adjustable depth stop is axially locked to the drill bit and a second position in which the adjustable depth stop is axially movable with respect to the drill bit. Moving the shuttle between first and second positions may comprise moving the shuttle along an axis substantially perpendicular to the longitudinal axis of the drill bit. Moving the shuttle between first and second positions may also comprise moving the shuttle along an axis substantially non-parallel to the longitudinal axis of the drill bit. The shuttle may further comprise a drill bit engaging surface, the drill bit further comprising a shuttle engaging surface, and one of the drill bit engaging surface and shuttle engaging surface may comprise a projection and the other comprises a recess.

[0015] The adjustable depth stop may further comprise a locking sleeve associated with the adjustment sleeve, where the locking sleeve is co-operable with the shuttle to move the shuttle between the first and second positions. The locking sleeve and shuttle further may have corresponding tapered sliding surfaces each of which forms an oblique angle with respect to the longitudinal axis of the drill bit, wherein axial movement of the locking sleeve moves the shuttle between the first and second positions. The shuttle may be axially fixed to the adjustment sleeve, and the locking sleeve may be axially translatable along the adjustment sleeve. Thus, moving the locking sleeve along the adjustment sleeve in a first direction may cause the shuttle to move toward the first position. Moving the locking sleeve along the

adjustment sleeve in a second direction may cause the shuttle to move toward the second position.

[0016] The adjustable depth stop may further comprise a spring associated with the adjustment sleeve to bias the shuttle in the first position. The adjustment sleeve may also have a distal stop surface configured to engage the housing.

[0017] In an alternative embodiment, a tool may be provided comprising a drill bit having proximal and distal ends and a longitudinal axis. The proximal end of the drill bit may be configured to connect to a driving attachment and the distal end may have a cutting surface for cutting a hole in a bone. The drill bit may also having an extended position corresponding to a first drilling depth into the bone. A housing may further be provided having proximal and distal ends and a longitudinal bore. The drill bit may be axially positionable within the bore, and the proximal end of the housing may further having a stop surface. The distal end of the housing may be associated with a bone portion. An adjustable depth stop assembly may be provided having proximal and distal ends and a longitudinal bore. The drill bit may be selectively axially lockable within the bore, and the distal end may comprise a stop surface configured to engage the housing stop surface. The assembly may further having unlocked and locked configurations so that the drill bit is axially translatable within the assembly when the assembly is in the unlocked position and the drill bit is axially fixed with respect to the assembly when the assembly is in the locked configuration. Thus, adjusting the distance between the respective stop surfaces of the housing and the depth stop assembly may adjust the first drilling depth into the bone portion.

[0018] The distal end of the housing may further be configured to engage a fastener hole of a bone plate, and the distal end may also have threads configured to engage corresponding threads of the hole in the plate. The distal end of the housing also may be configured to engage the fastener hole of the bone plate in order to fix the trajectory of the

drill bit with respect to the bone plate.

[0019] The drill bit further may have a retracted position in which the distal end of the drill bit does not extend distally beyond the housing distal end. The housing may further have a spring having a first surface associated with the housing and a second surface associated with the drill bit, the spring operable to bias the drill in the retracted position.

[0020] The drill bit further may have an axial engagement portion configured to engage a corresponding axial engagement portion of the housing to prevent the distal end of the drill bit from moving axially past the proximal end of the housing. The axial engagement portions of the drill bit and housing may comprise a pin and a shoulder, respectively.

[0021] The housing further may comprise proximal and distal housing portions, and the proximal housing may comprise a spring operable to bias the drill in the retracted position. The distal housing may comprise threads for engaging a bone screw hole of the bone plate. The proximal end of the distal housing further may comprise protrusion and recess elements configured to engage respective recess and protrusion elements on the distal end of the proximal housing to rotationally fix the two housings. The housing further may comprise a retainer for removably coupling the proximal and distal housings, such that the proximal and distal housings can be decoupled to facilitate cleaning and/or sterilization of the tool.

[0022] The proximal housing further comprising a proximal end having an increased diameter to allow gripping by a user. The proximal housing portion may also have a proximal stop surface configured to engage the adjustable depth stop assembly. The adjustable depth stop further may comprise an adjustment sleeve configured to slidably engage the drill bit, and may also have a shuttle member adapted to be slidable with respect to the adjustment sleeve between a first position in which the adjustable depth stop is axially locked to the drill bit and a second position in which the adjustable depth stop is axially

movable with respect to the drill bit. Thus, moving the shuttle between first and second positions comprises moving the shuttle along an axis substantially perpendicular to the longitudinal axis of the drill bit. Furthermore, moving the shuttle between first and second positions may comprise moving the shuttle along an axis substantially non-parallel to the longitudinal axis of the drill bit.

[0023] The shuttle further may comprise a drill bit engaging surface, and the drill bit may further comprise a shuttle engaging surface. One of the drill bit engaging surface and shuttle engaging surface may be a projection and the other may be a recess.

[0024] The adjustable depth stop further may comprise a locking sleeve associated with the adjustment sleeve, and the locking sleeve may be co-operable with the shuttle to move the shuttle between the first and second positions. The locking sleeve and shuttle further may comprise corresponding tapered sliding surfaces each of which forms an oblique angle with respect to the longitudinal axis of the drill bit such that axial movement of the locking sleeve may move the shuttle between the first and second positions.

[0025] The shuttle also may be axially fixed to the adjustment sleeve, and the locking sleeve may be axially translatable along the adjustment sleeve, such that moving the locking sleeve along the adjustment sleeve in a first direction may cause the shuttle to move toward the first position. Furthermore, moving the locking sleeve along the adjustment sleeve in a second direction may cause the shuttle to move toward the second position. The adjustable depth stop further may comprise a spring associated with the adjustment sleeve to bias the shuttle in the first position.

[0026] A method of drilling a hole to a desired depth is also disclosed. The method may comprise the steps of (a) providing a drill bit having a housing and an adjustable depth stop assembly, where the drill bit is slidably receivable within a bore in the housing, the drill bit further being receivable in, and adjustably lockable with respect to, a bore in the depth

stop assembly; (b) associating the housing with a bone segment; (c) adjusting the axial position of the depth stop assembly along the drill bit to position the housing a first distance from the depth stop assembly; and (d) drilling a hole into the bone with the drill bit such that the hole in the bone has a depth proportional to the first distance.

[0027] The step of associating the housing with a bone segment may further comprise engaging the housing with a fastener hole of a bone plate. The method may also comprise the step of fixing the trajectory of the drill bit with respect to the bone plate. The step of drilling a hole with the drill bit may comprise moving the drill bit through the fastener hole.

[0028] The method may comprise using a drill bit having at least one depth marking, wherein step (c) further comprises selecting a drilling depth by sliding the adjustable depth stop assembly to a position adjacent the depth marking. The method may also comprise associating the housing with the bone segment prior to the step of adjusting the axial position of the depth stop assembly along the drill bit to position the housing a first distance from the depth stop assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] For a better understanding of the nature and objects of the invention, reference should be made to the following detailed description, taken in conjunction with the accompanying drawings, in which:

[0030] FIG. 1 is a perspective view of an adjustable depth drill bit attached to a bone plate according to one embodiment of the present invention;

[0031] FIG. 2 is a cross-sectional side view of the adjustable depth drill bit of FIG. 1;

[0032] FIG. 3A is a side view of the adjustable depth drill bit of FIG. 1;

[0033] FIG. 3B is a expanded view of a portion of the adjustable depth drill bit of FIG. 1;

[0034] FIG. 4 is a cross-sectional side view of the distal housing of the adjustable

depth drill bit of FIG. 1;

[0035] FIG. 5 is a cross-sectional side view of the proximal housing of the adjustable depth drill bit of FIG. 1;

[0036] FIG. 6 is a cross-sectional side view of the threaded retainer of the adjustable depth drill bit of FIG. 1;

[0037] FIG. 7 is a cross-sectional side view of the shuttle sleeve of the adjustable depth drill bit of FIG. 1;

[0038] FIG. 8 is a perspective view of the removal sleeve of the adjustable depth drill bit of FIG. 1;

[0039] FIG. 9 is a cross-sectional side view of the removal sleeve of the adjustable depth drill bit of FIG. 1;

[0040] FIG. 10 is a perspective view of the locking sleeve of the adjustable depth drill bit of FIG. 1;

[0041] FIG. 11 is a side view of the locking sleeve of the adjustable depth drill bit of FIG. 1;

[0042] FIG. 12 is a top plan view of the sliding shuttle of the adjustable depth drill bit of FIG. 1;

[0043] FIG. 13 is a cross-sectional view of the sliding shuttle of the adjustable depth drill bit of FIG. 1;

[0044] FIG. 14 is an expanded partial cross-sectional view of the sliding shuttle of the adjustable depth drill bit of FIG. 1;

[0045] FIG. 15 shows the adjustable depth stop of the adjustable depth drill bit of FIG. 1; and

[0046] FIG. 16 is a cross-sectional side view of the adjustable depth stop of the adjustable depth drill bit of FIG. 1.

[0047] Like reference numerals refer to corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

[0048] Referring to **FIG. 1**, there is shown an exemplary drill assembly **10**, which may be adapted for use with a fixation device, such as for example, a spinal fixation plate **30**. While the drill assembly is disclosed in conjunction with a spinal fixation plate it is contemplated that the drill assembly may be used in conjunction with bone fixation plates used on or in any portion of the body. The drill assembly may be used with metal fixation plates as well as with bio-resorbable, polymer based, or any other bone fixation plates known in the art. Drill assembly **10** may include a drill bit **100** having a proximal end **40**, a distal end **50** and a longitudinal axis **20**. Drill assembly **10** also may include a housing assembly **200**, and an adjustable depth stop assembly **300** each disposed along the length of the drill bit **100**. The housing assembly **200** may be configured to orient and fix the drill bit with respect to the bone plate and bone (*i.e.* it may fix the drill trajectory), while the adjustable depth stop assembly **300** may comprise the depth adjustment mechanism of the device which may permit the user to pre-select the ultimate drilling depth into bone. The housing assembly **200** and the adjustable depth assembly **300** may comprise corresponding stop surfaces **258**, **322** that may cooperate to limit axial travel of the drill bit **100**, thereby limiting the drilling depth.

[0049] In general, to operate the adjustable depth drill bit **10**, a surgeon or 'user' determines the drilling depth desired for a particular procedure, which typically depends upon the length of screw selected for implantation. The user then may adjust the position of the adjustable depth stop **300** along the length of the drill bit **10** (described in more detail below) to provide the desired movement allowance of the drill bit **100**, as indicated by measured markings **110** on the drill bit **100**. Next, the distal end **220** of the housing **200** may be

positioned within a selected screw hole **32** of the bone plate **30**. Engaging the screw hole may serve to align the drill bit **100** along the appropriate drilling trajectory such that the bone screw hole (and thus the screw that will ultimately be driven into the hole), will assume the desired angular positioning with respect to the plate and the bone. Once drilling is begun and the drill is moved distally into the bone, the adjustable depth stop **300** automatically limits the total travel of the drill bit to the selected depth without further action from the user.

[0050] **FIG. 2** shows a truncated cross-section of the adjustable drill assembly 10 of **FIG. 1.** Drill bit **100** is shown as defining a longitudinal axis "**DA.**" Housing assembly **200** may generally comprise a distal housing portion **202**, a proximal housing portion **204** having an stop surface **258** for engaging the adjustable depth stop assembly **300**, a compression spring **206**, a washer **208**, a threaded retainer **210**, and a bushing **212**. Adjustable depth stop assembly **300** may generally comprise a shuttle sleeve **302** having a stop surface **322** for engaging stop surface **258** of the housing assembly **200**, a locking sleeve **304**, a removal sleeve **306**, a biasing spring **308**, and a sliding shuttle **310**.

[0051] As previously noted, the housing assembly **200** may function to align the drill bit within a targeted bone screw hole. The housing assembly may also serve as a protective cover for the drilling flutes of the drill bit **100** when the assembly is not in use, and may further serve as a gripping element to allow manipulation and installation of the device on the bone plate. The housing assembly **200** may comprise a bone plate engaging surface **222** at its distal end **220** (see **FIG. 4**), which in the illustrated embodiment may comprise threads configured to mate with a correspondingly threaded bone screw hole of a bone plate 30. Housing assembly **200** may also be configured to axially retain the drill bit between a fully recessed position and a fully extended position. In the fully recessed position, the distal end **104** of drill bit **100** may be contained within the housing **200** so that no portion of the drill bit extends beyond the housing distal end. In the fully extended position, the drill bit distal end

104 may extend beyond the distal end of the housing to engage a bone surface underlying a bone plate.

[0052] The housing may have a reduced diameter shoulder region **241** configured to axially engage a pin **212** positioned transversely through drill bit shaft **111**, thus preventing the drill from moving distally out of engagement with the housing. A spring **206** may be positioned within housing **200** and over a portion of the drill bit **100**. The spring **206** may have a proximal end **207** associated with a proximal shoulder **108** of the drill bit **100** and a distal end **209** positioned against a distal shoulder **253** of the housing **200**. When assembled, the spring **206** may axially bias the drill bit **100** in the proximal direction. A bushing **208** may be interposed between the proximal end of the spring **207** and the proximal shoulder **108** of the drill bit to protect the spring **206** from binding with the turning drill bit **100** during drilling. Thus, the bushing **208** may be press-fit into the housing **200** and may remain stationary when the drill bit **100** turns. This bushing **208** may be made of metal, polymer (*e.g.* Teflon, Polyether-ether-ketone (PEEK), etc.), or any other material known in the art to be suitable for such use.

[0053] Spring **206** and pin **212** thus may act to maintain the drill bit **100** in an initial "neutral" position in which the drill bit **100** is recessed within the distal end of the housing when not in use (the pin **212** acting to prevent the spring **206** from moving the drill bit too far in the proximal direction). To extend the drill bit from the housing in use, the user may apply a distal axial force to the drill bit sufficient to overcome the biasing force of the spring. When the distal axial force is removed (*e.g.*, when drilling is complete), the bias of the spring 206 once again may cause the drill bit **100** to recede fully within the distal end of the housing.

[0054] In order to adjust the device to achieve the desired drilling depth, the user may adjust the allowable length of travel of the drill bit **100** through the housing **200** by using the adjustable depth stop assembly **300**, which may be selectively positionable along the length

of the drill bit **100**. This selective positioning may be accomplished by sliding shuttle **310**, which may be axially retained within the depth stop assembly **300**, and which may have a surface that is selectively engageable and disengageable with a series of measured recesses **112** in the body of the drill bit **100**. The sliding shuttle **310** may slidingly engage a pair of tapered surfaces **334, 344** on the locking and removal sleeves **304, 306** such that moving the sleeves axially with respect to the shuttle may cause the shuttle to translate laterally with respect to the drill bit, thus moving the shuttle into, or out of, engagement with one of the drill bit recesses **112** (as will be described in more detail later). When the sliding shuttle **310** is disengaged from the drill bit recesses **112**, the adjustable depth stop may be moved axially along the drill bit **100**. Likewise, the adjustable depth stop may be fixed in a desired axial position by re-engaging the sliding shuttle **310** with the appropriate drill bit recesses **112**. In this manner, the distance between the stop surfaces **258, 322** of the proximal housing **204** and the shuttle sleeve **302**, respectively, may be adjusted. Since the housing **200** is fixed to the bone plate and the depth stop assembly **300** is fixed axially to the drill bit **100**, the distance between the housing and the depth stop assembly is equal to the total amount of distal travel afforded the drill bit **100**. Thus, the drilling depth is controlled by controlling the distance between the housing **200** and the depth stop assembly **300**.

[0055] In use, the surgeon may select the desired drilling depth by adjusting the distance between the two assemblies as described above, as measured by the markings **110** on the exterior of the drill bit **100 (Fig. 3A)**. This adjustment may be made either before or after the device is engaged with the bone plate. When drilling is commenced, the surgeon may apply an axial force to the drill bit to drive it distally into contact with the bone, thereby moving the drill bit out and away from the distal end of the housing. As previously noted, since the depth stop assembly moves axially with the drill bit and the housing assembly remains fixed to the plate, the total travel of the drill bit - and thus the drilling depth - is

limited (*i.e.* stopped) when the distal end stop surface **322** of the adjustable drill stop assembly **300** contacts the stop surface **258** of the proximal housing **204**.

[0056] Referring now to **FIG. 3A**, the drill bit **100** will be discussed in detail. Drill bit **100** may have proximal and distal ends **102, 104**, and a longitudinal axis **20**. The distal end of drill bit **100** may include drill flutes **106**, which can be standard drill flutes commonly used for drilling. Drill bit **100** can also be any other appropriate type of boring arrangement, such as for example, a needle, an awl, a punch, a burr, a reamer, or the like, provided the arrangement is configured to produce a desired opening or pilot hole of desired depth in the underlying bone for insertion of bone screws or other fastening elements. Drill bit 100 may also include a stop **108**, which may be formed by an increased-diameter portion **109** of drill bit **100**. Stop **108** may act as a retainer for washer **208**, described in more detail below, and may also provide a bearing surface for compression spring **206** which biases the drill bit **100** in the proximal direction to maintain the distal portion of the drill bit within the distal housing **202** when not in use. Drill bit **100** also may include one or more depth markings **110** arranged along at least a portion of its length, and these depth markings may correspond to a maximum distance which distal end **104** of drill bit **100** may protrude from housing **200** during drilling, as will be described in more detail below. Positioned along at least a portion of the drill bit length at a corresponding distance from depth markings **110**, and in increments equidistant to the depth markings **110**, are circumferential lock grooves **112**. Lock grooves **112**, shown in more detail in **FIG. 3B**, may be configured to receive a locking tab, such as a lock ridge **368** (Fig. 14) of sliding shuttle **310** of the adjustable depth stop **300** (further described below). In one embodiment there may be one or more lock grooves **112** spaced apart from each other by a distance **"d."** In the illustrated embodiment, there are fourteen lock grooves **112**, each spaced apart from each other by a distance **"d"** of about 1 millimeter (mm), such that the drilling depth of drill bit **100** can be adjusted in increments of about 1

mm. It is noted that the lock grooves **112** may be spaced apart by any appropriate distance **"d,"** to provide a desired incremental adjustment in maximum drilling depth. In one embodiment the lock grooves **112** themselves may each have a width **"w"** of about 0.55 mm and a height **"h"** of about 0.5 mm. The lock grooves **112** may taper outward, widening the lock groove **112** thickness toward the outer edge of the lock groove **112** for easier reception of the lock ridge **368** of the sliding shuttle **310** (further described below).

[0057] Returning to **FIG. 3A**, the proximal end **102** of drill bit **100** may have a coupling surface **115** configured for quick release attachment to a suitable drill handpiece (not shown) which may be either a manual or externally powered device. The coupling surface **115** can include, as shown in **FIG. 3A** a flat surface **114** on one side of drill bit **100** and a coupling groove **116** for releasably retaining drill bit **100** within the handpiece, although any suitable coupling arrangement may be used.

[0058] In one embodiment, drill bit **100** may be about 240 mm in length from proximal end **102** to distal end **104**. The drill flutes **106** may extend about 34 mm from the distal end **104** toward the proximal end **102**. The diameter of drill bit **100** at the drill flutes **106** may be about 3.0 mm and may increase to about 3.5 mm over a longitudinal span of about 0.5 mm at about 35 mm from the distal end **104**. The diameter of drill bit **100** may increase further to about 5.2 mm over a longitudinal span of about 0.5 mm, forming stop **108**, at a distance of about 120 mm from the distal end **104**.

[0059] **FIG. 4** shows distal housing **202** configured to encompass at least a portion of distal end **104** of drill bit **100** to guide the drill bit **100** along the desired trajectory relative to the bone plate **30** and bone screw hole **32**. Distal housing **202** may be a generally cylindrical housing defining a open or hollow central bore having a variable inner diameter configured to mate with corresponding variable outer diameters of the drill bit **100** and dimensioned to be slightly larger than the outer diameters of the mating portions of the drill bit **100** so that the

drill bit may slide and rotate freely therein. The distal-most end **220** of distal housing **202** is configured to engage a bone screw hole **32** of bone plate **30**. In one embodiment, the distal-most end **220** may comprise tapered threads **222** configured to correspond and engage matching inner threads of at least one bone screw hole of bone plate **30**. In an alternative embodiment, the distal most end **220** may comprise a smooth taper configured to match a smooth or threaded taper of at least one bone screw hole of the bone plate **30**. In a further embodiment, the taper angle of the distal most end **220** may be greater than, or less than, that of the bone screw hole. Any appropriate taper angle may be provided for the distal most end **220** as long as it allows the distal housing **202** to be aligned within the bone screw hole. Such alignment ensures the hole drilled into the bone may have the same trajectory as that of the bone screw hole, thus ensuring the associated bone screw will properly engage the bone screw hole when installed.

[0060] Distal housing **202** may further comprise a visualization slot **224** extending longitudinally along at least a portion of its length. Visualization slot **224** may function to provide a user with a window to see at least a portion of drill bit **100** within the distal housing during operation. This slot also may provide for easier cleaning and sterilization of the device after use, and may further provide an exit path for material removed by the drilling flutes during operation. The visualization slot **224** may be about 2 mm in width and about 45 mm in length. In an alternative embodiment, two or more visualization slots **224** may be provided on distal housing **202.** Distal threads **226** may be provided near the proximal end **228** of the distal housing **202** to facilitate engagement of the distal housing with the proximal housing **204** and the threaded retention sleeve **210**, as will be described below.

[0061] As shown in **FIGS. 4 and 5**, the proximal most end **228** of distal housing **202** may include a set of alternating recesses **242** and protrusions **243**. When assembled with proximal housing **204**, the recesses **242** and protrusions **243** of the distal housing **202** may

interlock with corresponding protrusions **240** and recesses **245** of the proximal housing **204**. The interlocking of the corresponding recesses **242, 245** and protrusions **240, 243** of the two housing segments may allow the two housings to transmit torque between them following assembly.

[0062] **FIG. 5** shows the proximal housing **204** in greater detail. Distal end **250** of proximal housing **204** may be configured to mate with the proximal end **228** of distal housing **202** through interaction of the recesses/protrusions **242, 243** of the distal housing **202** with the locking protrusions/recesses **240, 245** of the proximal housing **204**, respectively. Furthermore, distal housing **202** includes distal sleeve element **227** at its proximal end **228** which is configured to receive proximal sleeve element **251** of the distal end **250** of proximal housing **204**. The outer diameter of proximal sleeve element **251** may be slightly smaller than the inner diameter of distal sleeve element **227** such that when distal and proximal housing **202, 204**, respectively are mated, proximal sleeve element **251** may fit within distal sleeve element **227**.

[0063] Proximate to the distal end **250** of the proximal housing is a reduced-diameter throat portion **252** having an inner diameter **253** which may act as a guide for drill bit **100**, maintaining drill bit **100** in alignment with longitudinal axis **20** of the proximal and distal housings. In one embodiment, the inner diameter **253** of the throat portion **252** may be slightly larger than the outer diameter of the drill bit **100** such that the drill bit **100** can freely axially rotate and longitudinally translate within throat portion **252** while maintaining alignment with the longitudinal axis **20** of the housings. Proximal housing **204** may further comprise an externally threaded section **254** disposed adjacent the housing distal end **250**, and these threads may further be configured to mate with inner threads **270** of threaded retainer **210 (FIG. 6)**.

[0064] Proximal housing **204** may further include a longitudinal visualization slot

256. As previously described with respect to visualization slot **224** on the distal housing **202**, longitudinal slot **256** of the proximal housing **204** may be configured to allow the user to view the proximal portion of the drill bit **100** during use. Likewise, the slot **256** may also provide for easier cleaning and sterilization of the device after use, and may also provide an exit path for material removed by the drilling flutes during operation. The proximal most end of the proximal housing **204** may comprise a flared portion **255** suitable for gripping by the user. The flared portion **255** may have a stop surface **258** on the proximal end thereof, the stop surface **258** configured to engage stop surface **322** of shuttle sleeve **302** when the drill bit **100** reaches a maximum set drill depth.. The perimeter of flared portion **255** may further include a knurling or other surface texturing or roughening to facilitate user application of a rotational force to the proximal housing **204** to couple the distal portion of the housing **200** with bone plate **30** once the proximal housing **204** and the distal housing **202** have been assembled as described.

[0065] Referring now to **FIG. 6**, threaded retainer **210** is shown in more detail. In use, threaded retainer **210** may be used to fix the distal and proximal housings **202, 204** together. An internally threaded section **270** may be provided at the proximal end **276** of the retainer **210**, and this threaded section **270** may be configured to threadably accept the externally threaded sections **226, 254,** on the distal and proximal housings **202, 204,** respectively. These threaded connections may be provided to facilitate fit-up of the housing sections to enable the entire assembly to be disassembled after use for easy cleaning and sterilization. Thus, although the retainer and proximal and distal housings are disclosed as comprising threaded connections, these pieces may be connected using any suitable removable couplings or connections in the art.

[0066] To assemble the proximal and distal housings **202, 204**, threaded retainer **210** may be positioned so that its proximal threaded end **276** is placed over the distal end **220** of

distal housing **204** and slid toward the housing proximal end **228**. Once the retainer has been slid sufficiently far that threads **270** of the threaded retainer **210** engage the distal threads **226** of the distal housing, the retainer **210** may then be rotated until the internal threads **270** of the retainer pass through and out of engagement with the external threads **226**. The retainer **210** is thus loosely and slidably retained on the distal housing **202**. The proximal housing **206**, with drill bit **100** and spring **206** pre-installed therein, may then be engaged with the distal housing **202**. The sleeve elements **251**, **227** and respective protrusions and recesses **242**, **243**, **240**, **245** of the distal and proximal housings **202**, **204**, may then be engaged to align the housings along the longitudinal axis **20**. The two housings **202**, **204** then may be axially fixed together by engaging the proximal threads **270** of the retainer **210** with external threaded section **254** located adjacent the distal end **250** of the proximal sleeve **204**. As the retainer **210** translates along the proximal threads **270**, the reduced diameter lip **272** formed at the distal end **278** of the threaded retainer **210** engages the threaded proximal portion **226** of the distal housing **202**, pulling the distal housing **202** toward the proximal housing **204** and pressing the housings together.

[0067] In order to adjust the device to achieve the desired drilling depth, the user may adjust the allowable length of travel of the drill bit **100** through the housing **200** by using the adjustable depth stop assembly **300**, which may be selectively positionable along the length of the drill bit **100**. This selective positioning may be accomplished using **a** sliding shuttle **310**, which may be axially retained by the depth stop assembly **300**, and also may be selectively engageable and disengageable with a series of measured recesses **112** in the body of the drill bit **100**. Thus, the sliding shuttle **310** may act to selectively axially lock and unlock the depth stop assembly **300** and the drill bit **100**. The sliding shuttle **310** may be laterally movable with respect to the longitudinal axis "**DA**" of the depth stop assembly **300** and the drill bit **100** when the latter is inserted into the former. The lateral position of the

sliding shuttle **310** may be controlled using the removal and locking sleeves **306, 304** which are slidably mounted on shuttle sleeve **302,** and which may comprise opposing parallel planar surfaces **334, 344** against which the sliding shuttle **310** may slide during operation. These parallel planar surfaces **334, 344** may form an oblique angle α (FIGS. 9 & 11) with respect to the longitudinal axis "**DA**" of the depth stop assembly **300**, and the sliding shuttle **310** may have first and second tapered end surfaces **374, 376** which are angled to mate with respective parallel planar surfaces **334, 344.** When the removal and locking sleeves **306, 304** are slid axially along the shuttle sleeve **302,** the interaction between the angled surfaces **334, 344** of the sleeves and the correspondingly angled ends **374, 376** of the sliding shuttle **310** may cause the shuttle **310** to move laterally within the slot **342.** This lateral movement may cause lock ridge **368** of sliding shuttle **310** (FIGS. 13 & 14) to engage or disengage one of the corresponding recesses **112** in the drill bit **100**, depending upon whether the locking/removal sleeves **304, 306** are moved in the proximal or distal direction with respect to the shuttle sleeve **302**. Thus, sliding the locking/removal sleeves **304, 306** proximally along the shuttle sleeve **302** may cause the sliding shuttle **310** to engage one of the drill bit grooves **112**, while sliding the locking/removal sleeves distally along the shuttle sleeve may cause the sliding shuttle to disengage the drill bit groove.

[0068] When the sliding shuttle **310** is disengaged from the drill bit recesses **112**, the adjustable depth stop may be free to move along the length of the drill bit **100**. Likewise, the adjustable depth stop may be fixed in a desired axial position by re-engaging the sliding shuttle **310** with the appropriate drill bit recess **112**. In this manner, the distance between the engaging surfaces **258, 322** of the proximal housing **204** and the shuttle sleeve **302,** respectively, may be adjusted, and it is this distance which may ultimately control the amount of distal travel afforded the drill bit **100**. The drill bit **100** is axially movable with respect to the housing **200** and may be axially fixed to the depth stop assembly **300** as previously

described. In operation, as the user applies a distal axial force to the drill bit **100** to move it into contact with the bone, the depth stop assembly **300** travels along with the drill bit. When the distal end of the depth stop assembly **300** engages the proximal end of the housing **200**, further distal movement of the depth stop assembly **300** and drill bit **100** is prevented, and the drilling depth is thusly limited.

[0069] **FIG. 7** shows a longitudinal cross-section of shuttle sleeve **302** which may have proximal and distal ends **312, 314**, respectively, and a longitudinal axis **"DA."** The shuttle sleeve **302** may have a central bore **326** oriented coaxial with the longitudinal axis **"DA"** of the shuttle sleeve **302**. The central bore **326** may be sized to slidingly receive drill bit **100**, thus allowing the shuttle sleeve **326** to move axially along the drill bit **100**. Shuttle sleeve **302** may include a shuttle slot **324**, which may be configured to slidably receive sliding shuttle **310** **(FIG. 13)**. Shuttle slot **342** may have an axis substantially perpendicular to the longitudinal axis **"DA"** of shuttle sleeve **302**, so that the sliding shuttle **310** may slide within the slot **342** in a direction transverse to the shuttle sleeve bore **326** (and thus the drill bit **100**). In the illustrated embodiment, shuttle slot **324** may have a substantially rectangular or elongated central cross section with rounded ends **321, 323**. This elongated cross section may be provided to prevent the sliding shuttle **310** from rotating within the slot **324** during use. It is noted that the shuttle slot **324** may be provided with any appropriate geometric cross section (*e.g.* rectangular, square, triangular, round, elliptical, etc.) provided it may configured to mate with the cross section of the sliding shuttle to prevent the shuttle from rotating within the slot. Shuttle slot **324** may extend completely through two opposing lateral sides of shuttle sleeve **302** such that sliding shuttle **310** - when positioned within the slot **324** - may laterally protrude from either side of the sleeve **302**.

[0070] Shuttle sleeve **302** may further comprise a stop surface **322** at its distal end configured to engage a corresponding stop surface **258** of the distal housing **200** during

operation. The shuttle sleeve may also have an increased diameter flange portion **328** located adjacent the sleeve distal end **314**, the flange portion **328** being configured to allow grasping of the shuttle sleeve **302** by a user during operation.

[0071] **FIGS. 8 and 9** show the removal sleeve **306**, which, in operation, may cooperate with the locking sleeve **304** (Figs 10 & 11) to control the lateral position of sliding shuttle **310** within the shuttle slot **324** of the shuttle sleeve **302**, thus controlling the locking and unlocking of the depth stop assembly **300** with the drill bit **100**.

[0072] When assembled on shuttle sleeve **302**, removal sleeve **306** may share a common longitudinal axis **"DA"** with drill bit **100**, shuttle sleeve **302**, and locking sleeve **304**. Removal sleeve **306** may comprise a reduced diameter proximal portion **339**, an intermediate portion **338** and a distal portion **337**. The reduced diameter proximal end **339** may have a lip **336** sized to slidingly accept the drill bit **100**, and the intermediate portion **338** may be sided to slidingly accept the proximal end **312** of shuttle sleeve **302**.

[0073] The distal portion **337** of removal sleeve **306** may be configured to engage the proximal portion **340** of locking sleeve **304** (see FIGS. 8 and 9), to axially and rotationally lock the two sleeves together during use. Thus, the distal portion of removal sleeve **306** may comprise at least one axially extending engagement tab **332**, configured to engage a corresponding proximal recessed portion **343** of the locking sleeve **304**. Likewise, the removal sleeve **306** may comprise at least one distal recessed portion **333** configured to engage an axially extending engagement tab **342** of the locking sleeve **304**.

[0074] **FIGS. 10 and 11** show the locking sleeve **304** having proximal and distal portions **345, 347**. The proximal portion **345** may be configured to engage the distal portion **337** of removal sleeve **306** as previously described, and the distal portion **347** of locking sleeve **304** may be sized to slidingly receive the proximal end **312** of shuttle sleeve **302**. When assembled on shuttle sleeve **302**, removal sleeve **306** may share a common longitudinal

axis **"DA"** with drill bit **100**, shuttle sleeve **302**, and removal sleeve **304**.

[0075] As previously mentioned, the engagement tabs **332, 342** of the removal and locking sleeves **302, 304** may cooperate with locking sleeve **304** to control the lateral position of the sliding shuttle **310** within the shuttle slot **324**, thus controlling the locking and unlocking of the depth stop assembly **300** with the drill bit **100.** As such, the engagement tabs **332, 342** each have a tapered shuttle engaging surface **334, 344** (FIGS. 9 &11) which may be configured to slidingly engage corresponding tapered end surfaces **374, 376** of the sliding shuttle **310.** The tabs **332, 342** may be configured and oriented on the removal and locking sleeves **302, 304** so that when the sleeves are fit together, the tabs are diametrically opposed, which may result in the respective tapered shuttle engaging surfaces **334, 344** being parallel (*see* **FIG. 15**).

[0076] The tapered shuttle engaging surfaces **334, 344** may each be configured to form an acute angle α that is oblique to the longitudinal axis **"DA"** of the locking and removal sleeves **304, 306**. The angle α may be selected from the range of from about 1 degree to about 45 degrees. In the illustrated embodiment, α is about 10 degrees.

[0077] In the illustrated embodiment, engagement tab **332** tapers from a thick portion near the locking sleeve intermediate portion **338** to a narrower portion nearer the sleeve distal end **337**. Likewise, engagement tab **342** tapers from a narrow portion near the removal sleeve proximal end **345** to a thicker portion near the sleeve distal end **347**.

[0078] Referring now to **FIGS. 12-14**, the sliding shuttle **310** will now be described. As illustrated in **FIG. 12**, the sliding shuttle **310** may be a generally washer-shaped element having two generally flat parallel side portions **362** and **364**. Sides **362, 364** may be configured to be slidably receivable within corresponding surfaces **321, 323** of shuttle slot **324 (FIG. 7).** Offset from the center of the sliding shuttle **310** may be a bore **367** having a bore axis **"BA"** and an inner surface portion **366.** The bore **367** may be configured to have a

diameter larger than the outer diameter of the drill bit **100.** Disposed within at least a portion of the circumference of the inner surface portion **366** is a lock ridge **368**. Lock ridge **368** may protrude radially inward from the inner surface portion **366** toward the center of the bore **367**. Lock ridge **368** further may be configured to mate with lock grooves **112** of drill bit **100** when the drill bit is inserted into the bore **367** and the sliding shuttle **310** is pressed laterally against one of the lock grooves **112**. The inner surface portion **366,** including lock ridge **368** may have an inner diameter "**ID**" that is greater than the outer diameter of the drill bit **100**. Thus, when the drill bit **100** is substantially centered within the inner surface portion **366** of the sliding shuttle **310**, the drill bit **100** and sliding shuttle **310** may be free to slide axially with respect to each other. Likewise, when the sliding shuttle **310** is moved laterally with respect to this center position, lock ridge **368** may engage one of the grooves **112** in the drill bit **100** to axially fix the sliding shuttle **310** and drill bit **100** together.

[0079] Referring to **FIGS. 12, 13 and 14**, tapered end surfaces **374, 376** each may form an angle α with respect to the bore axis **"BA,"** and with axis "**DA**" when the device is fully assembled. As previously indicated, these tapered end surfaces **374, 376** are configured to correspond to tapered surfaces **334, 344** of the removal and locking sleeves, respectively.

[0080] Because the bore axis "**BA**" is offset from the central axis "**SA**" of the sliding shuttle **310,** the distance from the bore axis "**BA**" to the outer periphery of tapered surfaces **374, 376** differs. For ease of reference, the side of the shuttle comprising tapered engaging surface **374** will be referred to as "short side **370**" and the side of the shuttle comprising tapered engaging surface **376** will be referred to as "long side **372**." In the illustrated embodiment, the portion of lock ridge **368** adjacent the long side **372** of the sliding shuttle engages a respective drill bit groove **112** when the sliding shuttle **310** is located adjacent the distal-most portion of locking sleeve tapered surface **344**, as shown in **FIG. 2**

[0081] When the locking/removal sleeves **304/306** are moved distally along the

shuttle sleeve **302** so as to position the sliding shuttle adjacent the proximal-most portion of the removal sleeve tapered surface **334,** the sliding shuttle **310** is laterally translated so that the long side **372** is moved laterally away from the drill bit **100** (disengaging the shuttle from the grooves) and the short side **370** is moved laterally toward the drill bit. When the short side **370** of the sliding shuttle **310** is fully translated toward the drill bit **100,** its extension may not be sufficient to allow the portion of lock ridge **368** located adjacent the short side **370** to engage one of the drill bit grooves **112**

[0082] To assemble the adjustable depth stop assembly, locking sleeve **304** may be slid over the proximal end of sliding shuttle **310** and moved to a position distal of the shuttle slot **324.** The sliding shuttle **304** may then be inserted within shuttle slot **324** of shuttle sleeve **302** such that short side **370** and long side **372** of the sliding shuttle **310** both extend slightly beyond the outer circumference of shuttle sleeve **302,** as shown in FIGS. 2 and 16. Next, biasing spring **308** may be placed within the bore of the removal sleeve **306,** and the two pieces may be slid over the proximal end of shuttle sleeve **302.** The locking sleeve **304** and removal sleeve **306** may then be rotatably adjusted so that their complementary tabs **342, 332** may engage with respective recesses **333, 343** on the other sleeve, and so that the shuttle sleeve **302** may be properly engaged with the tapered inner surfaces **344, 334** of sleeves **304, 306** respectively. In particular, the inner surface **334** taper of sliding shuttle engagement tab **332** may engage the short side taper **374** and the tapered inner surface **344** of the sliding shuttle engagement tab **342** may engage the long side taper **376,** see FIG. 16. The locking and removal sleeves **304, 306** may then be fixed to one another using any appropriate fixation arrangement (*e.g.* laser welding, brazing, adhesive, etc.). FIG. 2 shows the assembled adjustable drill stop **300,** including the removal sleeve **306,** locking sleeve **304,** sliding shuttle **310,** and shuttle sleeve **302** engaged with drill bit **100.**

[0083] Referring to **FIGS. 15 and 16,** the operation of the adjustable depth stop **300**

will now be described. In its initial state, the biasing spring **308** of the adjustable depth stop assembly **300** biases the shuttle sleeve **302** away from the locking/removal sleeves. Owing to the interaction of the corresponding tapered surfaces **344, 334, 374, 376** of the locking/removal sleeves and the sliding shuttle **310,** this biasing causes the shuttle sleeve **302** (and so the sliding shuttle **310**) to reside adjacent the distal end of the locking sleeve **304,** thus causing the sliding shuttle **310** to laterally translate within the shuttle slot **324** such that lock ridge **368** of the sliding shuttle **310** engages one of the grooves **112** in the drill bit. The adjustable depth stop assembly **300** is thus locked to the drill bit **112.**

[0084] To release the adjustable depth stop **300** from drill bit **100** the user may apply a force in the distal direction to the removal sleeve **306** while simultaneously applying a proximal force to the shuttle sleeve **302**. When the user-applied force overcomes spring force the locking and removal sleeves 304 may move distally along the shuttle sleeve **302**, which in turn translates sliding shuttle **310** laterally within shuttle slot **324,** this time in the direction tending to separate the lock ridge **368** from the drill bit locking groove **112**. The drill bit **100** may now slide freely within shuttle sleeve **302**.

[0085] To select a desired drilling depth, the user may simply press the locking/removal sleeves while pulling back on the sliding shuttle, thus releasing stop assembly **300** from the drill bit **100** in the manner described above. The adjustable stop assembly **300** may then be moved along the drill bit **100** until the contact surface **322**of shuttle sleeve **302** lies adjacent the measured depth marking **110** corresponding to the desired drilling depth. The removal/locking sleeves may then be released, whereupon the spring may cause the sliding shuttle to engage the groove **112** in the drill bit **100** associated with the selected drilling depth.

[0086] Once the desired drilling depth has been selected, the distal end **220** of the distal housing **202** may be engaged with a targeted bone screw hole **32** of a bone plate **30,**

thus setting the appropriate drilling trajectory. Thereafter, a drilling device (either manual or powered) may be attached to the drill bit **100** proximal end **102** coupling. When drilling is begun, the user may simply apply a downward (distal) force to the drill bit **100** to overcome the force of spring **206**, thus causing the drill distal end **104** to emerge from the distal housing **202** to engage the bone. While drilling is being performed, the adjustable depth stop assembly **300** may remain axially fixed with respect to the drill bit **100**, and thus it may distally with the drill bit **100** as the drill tunnels into the bone. Since the housing **200** is axially fixed to the bone plate **30**, maximum selected drilling depth is achieved when contact is made between the respective stop surfaces **258**, **322** of the proximate housing **204** and the adjustable depth stop assembly **300**. In relation to the above method of use, it is noted that the drilling depth may be adjusted after the housing **200** has been engaged with the bone plate **30**.

[0087] It will be appreciated by one of ordinary skill in the art that the components of the invention may be constructed from a medical grade stainless steel that is tolerant of sterilization procedures and safe for use within the body. However, the device of the present invention may also be constructed from any suitable material that provides appropriate support for drilling bone holes. In one embodiment, the device may be constructed from a polymer based material such that the device is disposable following use. By way of example, but not limitation, suitable polymers may include ultra-high molecular weight polyethylene or the like.

Accordingly, it should be understood that the embodiments disclosed herein are merely illustrative of the principles of the invention. Various other modifications may be made by those skilled in the art which will embody the principles of the invention and fall within the spirit and the scope thereof.